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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	12

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,325	ELLIOTT ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *110-151* is/are pending in the application.

4a) Of the above claim(s) *126-151* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *110-125* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 110-148 are pending, however, claims 126-148 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Claims 110-125 are under current examination.

Claim Objections

Claim 112 is objected to because the word, "xtraction" appears missing an "e".

Claim 116 is objected to because the term "IGF-1" should be spelled out the first time it appears in the claim.

Claims 124 and 125 are objected to because the term, "quinaline" is not present in general or medical English dictionaries. For the interest of a compact prosecution, the term has been interpreted as "quinoline" in this Office action. Appropriate clarification is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 110-125 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for exposing the islets to nicotinamide *after* the steps of harvesting and extracting, does not reasonably provide enablement for doing so *before* the harvesting and extracting, and it does not reasonably provide enablement for obtaining increased benefit by extending the length of IGF-I treatment for those cells from piglets furthest from full term gestation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731, 737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided. The factors most relevant to this rejection are the scope of the claims relative to the state of the art, and whether sufficient amount of direction or guidance are provided in the specification to enable one of skill in the art to practice the claimed invention.

Claim 110 is directed to a method of preparing a xenotransplantable porcine islet comprising the step of exposing the islet to nicotinamide *before* the steps of harvesting or extracting. However, neither the prior art of record nor the specification teaches how the exposure could be done before the pancreas be harvested from the piglets, before the islets extracted from the pancreas, and the efficacy of such exposure when the islet cells are still embedded in the pancreatic tissue, and could not be fully exposed to the nicotinamide. Thus, the specification fails to provide an enabling disclosure commensurate in scope with the claims.

Claim 118 is directed to exposing islet cells to IGF-1 with a greater length for those cells obtained from the piglets with the youngest and/or oldest age (furthest from full term gestation). However, the specification fails to provide any teaching or support for such claim. The specification is silent regarding the correlation of the length of the IGF exposure and the age of the piglets, and when discussing the exposure time of IGF-I, the specification teaches, "*no increased benefit was found on culturing the islets with IgF-1 beyond a 24hrs period post isolation*" (page 17, lines 27-30), and "*No further benefit was achieved by increasing the concentration of IgF-1*" (page 17, lines 19-20). It appears that the specification teaches away from the instant claim.

It is noted that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. In re Goodman, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991). 35 U.S.C. § 112 requires that the scope of the claims must bear a reasonable correlation to the

scope of enablement provided by the specification to persons of ordinary skill in the art. In re Fisher, 166 USPQ 18, 24 (CCPA 1970).

Therefore, in view of the guidance provided, the state of the art and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 110-125 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 110 is vague and indefinite because claim does not recite a positive step or recitation indicating that the goal of the method has been resolved, which clearly relates back to the preamble.

Claim 113 is vague and indefinite because it recites, "the harvested pancreas is in a supportive mammalian albumin", the phrase encompasses various situations where the pancreas could be embedded, on top of the supportive mammalian albumin, or immersed in a medium comprising the mammalian albumin, it is unclear the association of the pancreas and the albumin, thus, the metes and bounds of the claim are uncertain.

Claim 113 is vague and indefinite because of the claim recitation, "non-human microbiological agents". The specification fails to define the term, and given the plain meaning of the term, microbiological agents do not encompass human beings. It is

unclear the meaning of the term in the context of the claims, thus, the metes and bounds of the claim are uncertain.

Claim 118 is vague and indefinite because the claim does not make clear the subject of the comparison for the word "greater", and the meaning of "either of IGF-1 or GPE" is unclear in the context of the claim. Moreover, "furthest from full term gestation" could encompass the fetus with the youngest age (e.g. –20 days) or the newborn with the oldest age (e.g. +10). It is unclear whether the phase embraces either or both situation. Thus, the metes and bounds of the claim are uncertain.

Claim 119 recites the limitation "their" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 119 is vague and indefinite because the meaning of the phrase, "wherein the exposure to IGF-1 is unrelated to their relationship with full term gestation" could not be determined in the context of the claims, thus, the metes and bounds of the claims are unclear. For the interest of a compact prosecution, the term has been interpreted as treating islets with IGF-1 at a fixed length of time regardless the age of the piglets from which the islet cells are obtained from.

Claim 124 is vague and indefinite because of the claim recitation, "associating". The specification fails to define the term, it is unclear the meaning of the term in the context of the claim, thus, the metes and bounds of the claim are uncertain.

Claim 125 is vague and indefinite because of the claim language "quinaline" is not defined by the specification or present in English dictionary, the meaning of the term could not be determined, thus, the metes and bounds of the claims are unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 110, 111, 113, 115, 120 are rejected under 35 U.S.C. 102(b) as being anticipated by *Rayat et al* (Diabetes 1998;47:1406-11).

The claims are drawn to a method of preparing a xenotransplantable porcine islet comprising harvesting the pancreas of piglets from –20 to +10 days full term gestation, preferably –7 to +10 days, extracting pancreatic β islet cells, and exposing the islets to nicotinamide after the extraction step, wherein the harvested pancreas is in a medium comprising mammalian albumin and trauma protecting agent free of microbiological agent. The specification fails to define the trauma-protecting agent, thus, any agent that promote cell growth and suppress apoptosis would be considered as meeting the claim limitation.

Rayat et al teach a method of preparing porcine islet cells as potential source for transplantation into humans (abstract) comprising harvesting the pancreas from

neonatal piglets at 1-3 days, extracting pancreatic islet beta cells, and culturing the islet cells with nicotinamide and bovine serum albumin (trauma-protecting agent) under sterile condition (free of microbial by including penicillin and streptomycin in the medium, paragraph bridging pages 1406-7). Thus, *Rayat et al* anticipate the instant invention.

Claims 110, 111, 115, 120, 123 are rejected under 35 U.S.C. 102(e) as being anticipated by *Elliott* (6,146,653 or 6,090,400).

Claim 123 is directed to subjecting the pancreas and the islets to a trauma-protecting agent and mechanically reducing the harvested pancreas.

Elliott teaches a method of preparing a xenotransplantable porcine islet (pig to mouse, column 2, lines 5-6) comprising harvesting the pancreas of piglets at near full term gestation (the full term for piglet is around 115 days, thus, -20 to +10 days is at or near the full term gestation), and treating the islet cells with nicotinamide and any compound exhibiting similar growth promoting and cytoprotective effects (column 1, lines 24-30). *Elliott* also teaches mechanically reducing the harvested pancreas (diced) in the presence of cytoprotective agents (column 2, lines 23-26). Thus, *Elliott* anticipates the instant invention.

The applied references have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 110, 111, 115, 120, 123 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. US patent 6,146,653 and 6,090,400 disclose the subject matter as now claimed, but the cited patents have different inventive entity. Further clarification is required as to who is the inventor of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 110 and 112 are rejected under 35 U.S.C. 103(a) as being obvious over *Rayat et al* (Diabetes 1998;47:1406-11), in view of *Brandhorst et al* (Transplant 1999;68:355-61, IDS).

Claim 112 is drawn to using human liberase in the step of islet cell extraction. *Rayat et al* teach using collagenase but not Liberase.

Brandhorst et al teach that a barrier for successful islet isolation is the intrinsic fragility of islets during pancreas digestion and using human Liberase could double the yield of islet cells compared to collagenease (abstract), "LOW-TEMPERATURE DIGESTION OF PORCINE PANCREATA USING LIBERASE HI COULD SERVE AS AN ESSENTIAL PREREQUISITE FOR SUCCESSFUL 1:1 XENOTRANSPLANTATION OF PIG ISLETS".

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Rayat et al, and Brandhorst et al*, by simply substituting collagenase with Liberase with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because it could enhance the yields of islet cells substantially. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 110, 113, 114, 116, 119, and 123 are rejected under 35 U.S.C. 103(a) as being obvious over *Rayat et al* (Diabetes 1998;47:1406-11), in view of *Clark et al* (Endocrinol 1990;126:1895-1903) and *Maysinger et al* (CA 2,216,055, IDS).

The claims are drawn to culturing the obtained islet cells in the presence of IGF-1, and human serum albumin (HAS), and extracting the islet cells by mechanical means in the presence of an islet trauma-protecting agent. *Rayat et al* do not teach these steps in the method of islet cell preparation.

Clark et al teach developing a defined medium comprising IGF-I and HAS for culturing islet cells of rats (abstract). They teach the need for developing the medium and the function of the components in the medium for long term sustained culture of adult as well as fetal islet cells (Introduction, and table 1). For islet cell extraction, they teach terminating the trypsin digestion with fetal bovine serum-containing medium, and obtaining the islet cells by aspiration of islets through stainless steel cannulae (mechanically reducing the harvested pancreas). Because the FBS promote cell growth, and protect cell membrane, thus, is considered as trauma preventing agent. *Clark et al* teach cultures for rat cells, not porcine.

Maysinger et al teach culturing mammalian islet cells in general in the presence of IGF-I (page 4, line 30), and one of more growth factors having anti-apoptosis effect on islet cells (trauma preventing agent, abstract). Evidently, the skilled artisan does not discriminate among the species of the mammalian for culture conditions of islet cells.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Rayat et al, Clark et al*, and *Maysinger et al* by simply including IGF-I and HAS and adding trauma protecting agent during the mechanical disassociation of pancreas with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the

claimed invention because the modified method enhances the viability and sustained survival of ex vivo cultured islet cells. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claim 117 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Rayat et al* (Diabetes 1998;47:1406-11), *Clark et al* (Endocrinol 1990;126:1895-1903) and *Maysinger et al* (CA 2,216,055, IDS) as applied to claims 110, 113, 114, 116, 119, 123 above, and further in view of *Saura et al* (Neuroendocrinol 1999 Jan 18;161-4).

Claim 117 is drawn to treating islet cells with GPE.

The combined teachings of *Rayat et al*, *Clark et al*, and *Maysinger et al* do not disclose that the N-terminal tripeptide of IGF-I would have the biological activity of the full length IGF-I.

However, before the instant effective filing date, *Saura et al* teach that the GPE does have the biological activity of full length IGF-I in the brain tissue (see particularly § Introduction).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Rayat et al, Clark et al*, and *Maysinger et al* by simply substituting full length IGF-I with the GPE tripeptide with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because it has been proven that GPE has the biological activity of IGF-I and has a smaller size (easier for delivery), thus providing

additional means for similar biological activity. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 110, and 120-122 are rejected under 35 U.S.C. 103(a) as being obvious over *Rayat et al* (Diabetes 1998;47:1406-11), in view of *Pu et al* (Brit J Pharmacol 1996;118:1072-8).

Claims 121 and 122 are drawn to treating pancreas or islets with lignocaine as the trauma-protecting agent in the process of preparation. *Rayat et al* fail to teach using lignocaine.

Pu et al teach that addition of lignocaine in isolated rabbit heart tissue culture could restore the contractility of myocardiocytes after minor traumatic injury (myocardial contusion), and thus lignocaine could be used as a therapeutic agent for tissue recovery from minor trauma (abstract, and § 5).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the methods taught by *Rayat et al,* and *Pu et al* by including lignocaine in the pancreas harvesting and extracting process with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because the lignocaine has been proven effective in restore minor injury of cultured organ cells. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 110, 124 and 125 are rejected under 35 U.S.C. 103(a) as being obvious over *Rayat et al* (Diabetes 1998;47:1406-11), in view of *Boss et al* (US 6,432,710) and *Champion et al* (US 4,850,993).

Claims 124 and 125 are drawn to culturing islet cells in the presence of quinoline antibiotics, preferably ciproxin. *Rayat et al* use penicillin and streptomycin, but not quinoline.

However, before the instant effective filing date, *Boss et al* teach that quinoline antibiotics is useful in preventing mycoplasmal contamination (column 13, line 64-column 14, line 4). *Champion et al* teach that ciproflaxin (ciproxin) belongs to quinoline antibiotics (column 2, line 14).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Rayat et al* by including ciproxin in the culture medium for preventing mycoplasmal contamination with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the method because mycoplasmal contamination is a concern for many cell culture laboratories and ciproxin has been proven effective for prevention. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 110, 111, 115, 120, and 123 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 13, and 14 of U.S. Patent No. 6,146,653.

The reference patent qualifies as prior art under this provision because there is one common inventor and no common assignee between the instant application and the cited patent.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 110, 111, 115, 120, 123 of the present application is drawn to a method of preparing a xenotransplantable porcine islet comprising harvesting the pancreas of piglets from –20 to +10 days full term gestation, extracting pancreatic β islet cells, and exposing the islets to nicotinamide, whereas claims of the cited patent are drawn to a preparation of porcine islet cells for xenotransplantation prepared by the presently claimed method, which has been fully disclosed in the specification of the cited patent.

Accordingly, the claimed processes in the copending and the present application are obvious variants. Therefore, the inventions as claimed are co-extensive.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Patent Examiner
Art Unit 1632

QJL
July 14, 2003